

## **I. REMARKS**

### **(a) Status of Claims:**

Claims 7-39 have been examined and are rejected on various grounds. The grounds of rejections are addressed in detail below.

### **(b) Informalities:**

Objection to the drawings previously indicated by the Examiner is acknowledged. Correction will be made where needed upon allowance of this application.

Notification to comply with the requirements directed to applications containing nucleotide and/or amino acid sequence is also acknowledged. Submitted herewith is a revised sequence listing in compliance with 37 CFR §1.821-1.825.

### **(c) New Matter Rejection and Priority of the Instant Application:**

All pending claims 7-39 stand rejected as allegedly containing new subject matters not described in the priority specifications. It is argued that the priority specifications do not provide written support to the recitation of certain density or numerical requirements as well as the "free of cross-contamination" limitation. The Office Action concludes that the priority date for all pending claims is July 30, 1996, which is the filing date of the most recent priority application U.S. Serial No. 08/688,488. Applicants respectfully traverse.

As an initial matter, Applicants submit that the original claim elements, now being objected, were presented in the Preliminary Amendment of record (November 24, 1998). The Preliminary Amendment was submitted along with the instant continuation application filed on the same day. Written support for the objected to terms was detailed in that Amendment as well as the referenced Response of April 20, 1998. Copies of the November 24, 1998 Preliminary Amendment and the April 20, 1998 Response are attached herewith for reconsideration.

With respect to the lack of contamination limitation, Applicants submit that the limitation is inherent in the description of Applicants' microarrays contained in this application, as well as in parent, grandparent, great-grandparent and great-great-grandparent applications. As explained in the April 20, 1998 Response, "the limitation follows from the fact that Applicants' microarrays are created by individually depositing the desired DNA at each region in the microarray, necessarily precluding any significant degree of cross-contamination at any region in the microarray by DNA sequences applied to other regions in the microarray. *See generally* specification at 11-12, Serial No. 08/514,875 at 10-21, Serial No. 08/477,809 at 13-18, and Serial No. 08/261,388 at 8-14." Thus this limitation does not constitute new matter. It is fully supported by the earliest priority specification.

With respect to certain density or numerical requirements, the previously submitted documents of record point out that the objected to terms find support in the earlier priority specifications. For instance, the paragraph bridging pages 8 and 9 of the April 20, 1998 Response states the following:

"Added independent claim 21 (and added claims 22-33, which depend therefrom) claims Applicants' microarray invention in a product-by-process format. Step (a) recites the step of depositing between about 0.002 nl and about 2 nl of a solution comprising a selected, isolated polynucleotide at a discrete region on the surface of the substrate bearing the microarray. That volume range is literally supported in this application (*e.g.*, at 12:5-6), the parent application (*e.g.*, at 14:2 and Table I), the grandparent application (at 16:34 and Table I), and the great-grandparent application (*e.g.*, at 11:31 and Table I). Step (b) recites that step (a) is repeated until a microarray of 400 or more regions is formed, at a density between about 62,500 and 625 regions/cm<sup>2</sup>. The limitation of 400 or more regions is supported in this application and the parent, grandparent, and great-grandparent applications, as discussed above. The density range of between about 62,500 and 625 regions per cm<sup>2</sup> also is supported by all those applications. Those densities flow directly from the disclosure in all the applications that (1) the regions in the microarray may be formed by drops that are between about 0.002 nl and 2 nl, which correspond to disclosed region diameters of between about 20 and 200  $\mu$ m, and (2) the distance between the regions in the microarray preferably

should be separated from one another by about the same distance as the diameter of the regions.”

The Examiner is urged to review the enclosed prior submissions of record. Reconsideration of the priority date granted to all of the pending claims is respectfully requested. In particular, Applicants point out that independent claim 36 and its dependent claim 37 do not recite any of the objected to terms. These two claims are entitled to the earliest priority date of the great-great grandparent application of June 17, 1994. The art rejections directed to these two claims (see below) are thus improper.

**(d) Rejections under 35 U.S.C. §102(e) and 35 U.S.C. §103**

The Office Action cites U.S. Patent Nos. 6,013,440 (by Lipshutz et al.) and 5,723,320 (by Dehlinger) against all pending claims. The Lipshutz patent application was filed on March 10, 1997 claiming priority to a provisional application dated March 11, 1996. Thus, the earliest possible priority date of this reference is March 11, 1996. The Dehlinger patent application was filed on August 29, 1995, more than a year after the filing of Applicants’ earliest priority specification.

With respect to claims 36 and 37, Applicants submit that these two cited patents are improper 102(e) and/or 103(a) references because neither reference was filed before the invention thereof by the Applicants for patent. Determination of the priority date is a claim-by-claim analysis. This means that claims must be examined individually and not simply as a group of “all pending claims.” Because claims 36 and 37 do not recite any of the objected to terms including “comprises 400 or more regions,” their priority dates are not contested. The Office Action does not provide any reason as to why these two claims are not supported by the earliest priority application as filed. Withdrawal of this rejection and allowance of claims 36-37 are respectfully requested.

U.S. Patent Nos. 6,013,440 (by Lipshutz et al.) and 5,723,320 (Dehlinger) also do not anticipate the rest of the claimed subject matter or render the subject matter obvious. As noted

above, the characterization of the priority date of the remaining pending claims is inaccurate. To the extent that the objected terms and hence the rejected claims as whole are entitled to the priority date predating the filing date of the two cited references, the rejections under 35 U.S.C. §102 (e) and §103(a) are improper. Withdrawal of these rejections are respectfully requested.

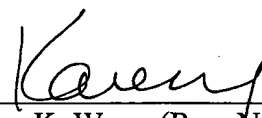
### III. CONCLUSION

Applicants respectfully submit that the above amendments and remarks fully respond to the rejection made in the Office Action mailed March 26, 2001. Applicants submit that the claims as amended are in allowable form and condition. If the Examiner believes a telephone interview would further prosecution of this case, the Examiner is invited to call the undersigned at (650) 463-8100.

It is believed that a sufficient extension fee is included; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to deduct said fees from Arnold White & Durkee Deposit Account No. 01-2508 12665.0009.CNUS01.

Respectfully submitted,

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Karen K. Wong (Reg. No. 44,409) for  
Glenn W. Rhodes (Reg. No. 31,790)

HOWREY SIMON ARNOLD & WHITE  
750 Baring Drive  
Houston, Texas 77210-4433  
(650) 463-8100  
Attorneys for Applicants